

## **REMARKS**

In the Final Office Action mailed October 17, 2007, claims 39-53, 57, 60, 74-76 and 87-94 were pending. Each of claims 39-53, 57, 60, 74-76 and 87-94 currently stands rejected. In this response, claim 39 has been amended to more clearly define the claimed subject matter. In view of the following remarks, reconsideration and allowance of the present application as amended and including claims 39-53, 57, 60, 74-76 and 87-94, are hereby requested.

### **Claim Rejections**

As an initial matter, Applicant acknowledges and thanks the Examiner for the indication in the outstanding Action that the previously-asserted rejection of claims 39-53, 57, 60, 74-76 and 87-94 under 35 U.S.C. §112, first paragraph, is withdrawn. However, claims 39, 49, 57, 74, 76 and 88 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 3,079,299 to Heilig (hereafter "Heilig"); claims 40-50, 52, 53, and 60 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Heilig in view of U.S. Patent No. 6,217,890 to Paul et al. (hereafter "Paul") and in further view of U.S. Patent No. 6,103,245 to Clark et al. (hereafter "Clark"); claims 51 and 52 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Heilig in view of U.S. Patent No. 5,330,756 to Stuart et al. (hereafter "Stuart"); claims 74, 75, 87, 89, 93 and 94 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Heilig in view of U.S. Patent No. 5,881,925 to Ando (hereafter "Ando"); claims 90 and 91 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Heilig in view of U.S. Patent No. 5,169,037 to Davies et al. (hereafter "Davies"); and claims 90 and 92 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Heilig in view of U.S. Patent No. 5,249,747 to Hanson et al. (hereafter "Hanson"). For at least the reasons that follow, each of claims 39-53, 57, 60, 74-76 and 87-94 is submitted as patentable over the cited references.

As indicated above, claims 39, 49, 57, 74, 76 and 88 stand rejected as being anticipated by Heilig. It is well established that "an invention is anticipated if the same device, including all the claim limitations, is shown in a single prior art reference. Every

element of the claimed invention must be literally present, arranged as in the claim.” Richardson v. Suzuki Motor Co. Ltd., 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The claims must not be treated as “mere catalogs of separate parts, in disregard of the part-to-part relationships set forth in the claims and that give the claims their meaning.” Lindemann Maschinenfabrik GMBH v. American Hoist and Derrick Company et al., 730 F.2d 1452, 1459, 221 USPQ 481, 486 (Fed. Cir. 1984). As a result, a reference that coincidentally lists features of a claim without describing the claimed arrangement, relationship, and organization of such features cannot anticipate.

Applicant submits that Heilig fails to teach, suggest or disclose the limitations of the lone independent claim 39. For example, claim 39 recites, among features and elements, “. . . wherein the dispenser is not an aerosol device . . . .” Applicant has previously traversed the Patent Office’s position that Heilig discloses a dispenser that is not an aerosol device. See e.g., Response to Office Action filed July 18, 2007. However, despite the distinctions submitted in Applicant’s prior response, the outstanding Office Action has maintained the Patent Office’s position that Heilig discloses a dispenser that is not an aerosol device. In support of its position, the outstanding Office Action recites the following in the paragraph bridging pages 17-18:

The Examiner disagrees because although Heilig teaches a treatment for diaper rash primarily through an aerosol, Heilig [sic] teachings are taken as a whole. Heilig does not discourage the use of the composition through other means. In particular, Heilig teaches that “The primary object of the invention is to provide a self-propelling fluid medicinal ointment composition adapted to be atomized from a fluid-tight container and which, when applied directly as a fine spray or mist to the part of the body to be treated. . . .” (see column 1, lines 30-34.) Therefore, since there are other atomizing containers other than an aerosol known in the art, the composition is thus adapted to be dispensed from a variety of atomizers that does not have to include an aerosol device.

Contrary to the assertion of the Office Action, Heilig only describes a composition delivered by an aerosol delivery mechanism. Moreover, when the teachings of Heilig are taken as a whole, it is clear that it discourages the delivery of the

composition through any other means. In fact, as will be established below, not only is the use of an aerosol spray the only delivery mechanism disclosed in Heilig, the use of propellant gases in an aerosol delivery mechanism is critical and necessary to achieve the objects set forth by Heilig. Likewise, Heilig does not provide a disclosure broad enough to include a dispenser that is not an aerosol device.

In support of its overly-broad interpretation of Heilig, the Office Action relies on the disclosure of Heilig that its primary object “. . . is to provide a self-propelling fluid medicinal ointment composition adapted to be atomized . . . .” The Office Action appears to overlook the fact that even this broad indication of its primary object is to provide a self-propelling fluid. Particularly, Applicant submits that providing a “self-propelling” fluid necessarily means providing an aerosol fluid. Indeed, Applicant’s position is supported by the full disclosure of Heilig, in that the only type of self-propelling fluid it discloses is an aerosol. More specifically, Heilig provides several examples of “self propelling ointment compositions according to the invention.” See, column 3, lines 6-8. In each of the examples, the “self-propelling” ointment compositions include very high percentages of inert volatile propellant. For simplicity sake, the following table lists each of the examples along with its percentage by weight of propellant. (Examples taken from column 3, line 10 to column 5, line 4).

Example:	Propellant (% by weight)
1	70.00
2	70.00
3	90.00
4	88.3915
5	89.8675
6	95.458
7	95.458
8	95.2189

Of these examples, Heilig indicates that the compositions of examples 7 and 8, which include greater than 95% propellant by weight, are preferred. See, column 5, lines 5-7. This preference clearly emphasizes Heilig's reliance on an aerosol delivery mechanism to properly deliver the disclosed compositions. Moreover, the teachings of Heilig as a whole, including the inclusion of a high percentage of propellant gas in each example clearly indicates that 1) Heilig intended "self-propelling" fluid to refer to an aerosol fluid and 2) the compositions of Heilig are only adapted to be dispensed from an aerosol delivery mechanism. Likewise, the compositions of Heilig are not adapted to be dispensed from a variety of atomizers, as suggested by the Office Action.

In view of the foregoing, Applicant submits that Heilig does not disclose a dispenser that is not an aerosol device. In deed, with part of its primary object being directed to providing a self-propelling fluid medicinal ointment, and with all examples of a "self-propelling" fluid in the form of an aerosol spray, Applicant submits that Heilig's disclosure is limited to an aerosol delivery mechanism. Likewise, Heilig fails to disclose each element of independent claim 39.

As a further matter, contrary to the suggestion of the Office Action, Heilig clearly discourages delivery of the medicinal composition through means other than an aerosol delivery mechanism. In particular, Heilig is replete with indications of advantages provided by using an aerosol delivery mechanism. For example, it discloses that the "properties of the polyethylene base employed in the composition of the present invention are greatly enhanced and other advantageous properties obtained when the base is incorporated as an ingredient in an aerosol medicinal ointment composition . . . ." See, column 2, lines 1-5. In still another example, Heilig discloses that previous ointments containing polyethylene did not achieve "the outstanding results which have been obtained by utilizing the polyethylene base and medicament in an aerosol." See, column 2, lines 20-24. In yet another example, Heilig discloses "[w]hen neomycin undecylenate is combined with the polyethylene ointment base in an aerosol composition, it has been found to be unusually effective . . . ." See, column 3, lines 2-4. As a further example, Heilig discloses that "[t]he aerosol compositions of all the examples have been used effectively in the treatment of burns and other wounds." See,

column 5, lines 20-22. As an even further example, it is disclosed that the aerosol composition of example 6 was used on skin lesions with excellent results. See, column 5, lines 35-41. It is also disclosed that the aerosol composition of example 6 “provided a superior method for the treatment of lesions of the skin where the continuity of the skin is disturbed.” See, column 5, lines 53-55. In yet a further example, with respect to the composition of example 7, Heilig discloses that “[u]nusual and unexpected results were obtained with a first-aid aerosol spray . . . in the treatment of burns and other conditions.” See, column 5, lines 56-60. In addition to these examples, Heilig also provides (beginning at column 6, line 32) four specific advantages from the application of the aerosol mixture. These examples clearly impress upon those of skill in the art that Heilig discloses only aerosol fluids delivered with an aerosol delivery mechanism. Likewise, contrary to the suggestion of the Office Action, those having skill in the art, when considering Heilig as a whole, would clearly be discouraged from delivering the composition of Heilig through any other means but an aerosol delivery mechanism.

It should also be appreciated that an additional part of the primary object of Heilig is “to provide a breathing covering of polyethylene filaments from which the medicant is rapidly released to the treated area of the body.” See, column 1, lines 34-37. As would be appreciated by those skilled in the art, porosity and breathability of a skin coating are particularly important when treating a skin lesion or burn, with treatment of both being emphasized in Heilig. Moreover, Heilig clearly establishes that the advantages provided by the breathing film are at least partially attributed to delivery of the composition through an aerosol delivery mechanism. For example, Heilig discloses at column 2, lines 6-19:

When the aerosol ointment composition is atomized onto the affected area of the body, the polyethylene resin provides a breathing film which permits access of air and oxygen to the affected area of the body and facilitates the rapid release of the medicant to the affected area, thereby accelerating the healing of the infections, burns and other wounds. The propelling of the ointment with a liquefied gaseous propellant cooperates with the structural characteristics of the polyethylene in such a way that the filaments of the polyethylene resin are interlaced in a loose

dispersion over the affected area of the body to provide a breathing covering permitting the access of air and oxygen and the rapid release of the medicant to the affected area.

As a further example, Heilig discloses at column 7, line 73 to column 8, line 4:

The polyethylene and propellant in the composition cooperate in such a way that the polyethylene filaments are interlaced in a loose dispersion over any burned or affected area when sprayed by the propellant. A much more porous and spongy structure is produced as a result of the propellant gas leaving the sprayed particles of the base, which occurs almost instantly.

As yet another example, Heilig discloses at column 9, lines 7-15:

Furthermore, the mixture of the propellant gases permits the application of the correct amount of ointment in a manner such that the effective ingredients of the ointment are held on the affected area of the skin by a lattice of polyethylene filaments which are loosely interlaced over each other as they are propelled onto the affected area by the propellant, thereby providing a breathing film which permits access of air to and accelerates the release of the medicant to the affected area.

As a further matter, Heilig discloses that the aerosol sprayed ointment provides “superior breathing characteristics.” See, column 6, lines 70-71. Moreover, one of the listed advantages from the application of the aerosol mixture is that it “. . . permits the passage of fluid and vapors through it . . .” thereby preventing the collection of a culture for bacterial and fungal growths. See, column 6, lines 52-58. Additionally, when compared to ointments spread mechanically in a layer, “the oxygen transfer by the aerosol sprayed ointment base was definitely faster than the oxygen transfer through the same ointment when spread mechanically in a layer.” See, column 7, lines 35-41. In view of the foregoing breathability advantages provided by applying the composition with an aerosol mixture, Applicant respectfully submits that Heilig again discourages the delivery of the composition through any means other than an aerosol delivery mechanism. Moreover, Heilig’s emphasis on providing an ointment with superior

breathability, facilitated by delivery with an aerosol, further indicates that Heilig only contemplated delivery of the composition via an aerosol delivery mechanism.

Despite the foregoing distinctions provided between the subject matter of claim 39 and the disclosure of Heilig, Applicant has amended claim 39 to further distinguish Heilig in order to expedite prosecution of the subject application. Particularly, claim 39 now recites, among other features and elements, “passing the composition through the mechanism to atomize the composition and to propel the atomized composition toward the skin treatment area to provide a moisture barrier over the skin treatment area.” Support for the amendment to claim 39 may be found, for example, in paragraph [0035] of the as-published subject application. As indicated above, the composition of Heilig exhibits superior breathing characteristics, including for example, passage of water through the composition into contact with an affected skin area. See e.g., column 6, lines 52-58. Moreover, in view of the distinct advantages Heilig provides with respect to the breathability of its compositions applied with an aerosol, Heilig clearly teaches away from modifying its composition to provide a moisture barrier over a skin treatment area. Likewise, those having skill in the art would not modify the composition of Heilig to arrive at the invention of claim 39. Accordingly, for at least these reasons, claim 39 is further submitted as patentable over Heilig.

In view of the foregoing, Applicant respectfully requests withdrawal of this rejection and allowance of claim 39. Each of claims 49, 57, 74, 76 and 88 depends from claim 39 and is submitted as patentable for at least the reasons supporting the patentability of claim 39.

As indicated above, pending claims 40-53, 60, 74, 75, 87 and 89-94 stand rejected as being unpatentable under 35 U.S.C. §103(a) over various combinations of references. Applicant initially points out that each of the claims rejected under 35 U.S.C. §103(a) depends, directly or indirectly, from independent claim 39. For the reasons set forth above, the only ground for rejecting claim 39 set forth in the Action has been overcome and claim 39 is in condition for allowance. It is axiomatic that all dependent claims depending from an allowable base claim are also allowable for at least the same reasons that the independent claim is allowable. As such, Applicant submits that the rejections of

dependent claims 40-53, 60, 74, 75, 87 and 89-94 cannot be sustained for at least this reason.

The rationale provided in the Action in support of rejections of claims 40-53 and 60 over combinations of Heilig with Paul, Clark and Steuart is based upon a theory that persons skilled in the art would pluck ingredients out of the compositions described in Paul, Clark and Steuart, place them in the composition described in Heilig and deliver them to a treatment area using the aerosol delivery mechanism described in Heilig. Applicant submits that this rationale fails to establish a *prima facie* case of obviousness under Section 103(a) for several reasons, the most predominant of which is that the combinations, even if made, fail to produce the subject matter recited in the pending claims. The primary reference cited in each combination, the Heilig patent, describes an aerosol composition and an aerosol delivery mechanism, while each of the pending claims in the present application recites an atomizing spray dispenser that is “not an aerosol device.”

The outstanding Office Action appears to maintain this rejection based on its position that Heilig discloses a dispenser other than an aerosol device. However, as clearly established above, Heilig is solely directed to the use of an aerosol delivery mechanism and entirely discourages delivery of the composition through any other means. As such, combinations of these secondary references with Heilig for the purpose of modifying the disclosure of Heilig to include additional ingredients described in the cited secondary references, does not overcome the insufficiencies in Heilig to teach or suggest the subject matter of the present claims. The incorporation of ingredients from other references into the composition described in Heilig would not alter that the Heilig delivery system is an aerosol delivery system. In view of the above, Applicant submits that the Action fails to make a *prima facie* case that the claimed subject matter is obvious over the combination of Heilig with Paul, Clark or Steuart, because each of these combinations would result in an aerosol-type delivery system, and the claims pending in the present application recite an atomizing spray dispenser that is “not an aerosol device.”

With regard to the rejections of claims 74, 75, 87, 89 and 90-94 in the Action over combinations of Heilig with Ando, Davies and Hanson, the Examiner stipulates in the Action that, (1) “Heilig does not teach a pump spray dispenser... a pressure release device...[a]



piston-style dispenser...[or] a manually actuated or reciprocating actuator spray delivery mechanism,” (see Office Action Page 12), (2) “Heilig does not teach a bag-in-can-style dispenser, wherein the pressurized compartment is a polymeric bag received inside a rigid can or wherein the pressure is maintained upon the composition by a pressurizing gas received in the can and externally to the bag” (see Office Action Page 14), and (3) “Heilig does not teach a bag-in-can-style dispenser, wherein the pressurized compartment is a polymeric bag received inside a rigid can. Also, an elastic shape-memory bag wherein the pressure is maintained upon the composition by maintaining the bag in an expanded state is not taught.” See, Office Action page 16.

The rationale provided in the Action in support of rejections of claims 74, 75, 87, 89 and 90-94 over combinations of Heilig with Ando, Davies and Hanson is based upon assertions that a person skilled in the art would select one of the non-aerosol delivery mechanisms described in the secondary references to deliver the composition described in Heilig, i.e., would substitute a non-aerosol delivery mechanism for the aerosol delivery mechanism described in Heilig. Applicant submits that this rationale also fails to establish a *prima facie* case of obviousness under 35 U.S.C. §103(a) for several reasons, the most predominant of which is that Heilig clearly establishes a preference for an aerosol delivery mechanism to provide various advantages. Particularly, as indicated above, Heilig is replete with indications of advantages and superior characteristics associated with the composition in an aerosol form. Moreover, the preferred breathability aspects of the Heilig composition, which are disclosed as one of the primary objects of the inventions, are clearly described as being achieved by virtue of the aerosol delivery mechanism. Likewise, in view of the necessity of and advantages provided by the aerosol delivery mechanism, those having skill in the art would not modify Heilig to deliver the composition through any other means.

As a further reason, the suggested combination of references would render the subject matter described in Heilig unsuitable for its intended purpose. The delivery system described in Heilig involves a highly viscous ointment that can only be delivered as described therein if it is first dispersed in a very large amount of “inert volatile propellant” under high pressures to enable it to be delivered via an aerosol mechanism. Considering Examples 1 through 8 set forth in Heilig at Columns 3-5, it is seen that each formulation includes at least 70% inert

volatile propellant by weight, and some of the preferred formulations include much higher proportions of inert volatile propellant, up to more than 95% by weight. Absent this aerosol mechanism, which relies on very high proportions of volatile propellants, the “ointment base” described in Heilig could not be sprayed, and would therefore be unsatisfactory for its intended use. Therefore, Applicant traverses these rejections on the grounds that a person of ordinary skill in the art would not modify the references as asserted in the Action and because the combinations asserted in the Action would render Heilig unsuitable for its intended purpose.

The Action cursorily states that one or more of the mechanisms described in the secondary references can be used to “spray a mixture of liquid and powder,” (*See* Office Action, Page 12, line 17). The Examiner appears to be suggesting that an aerosol dispenser and a non-aerosol dispenser would have been expected by a person skilled in the art to be interchangeable for delivering any composition having liquid and solid components; however, Applicant traverses this implication. While aerosol delivery and non-aerosol delivery might be interchangeable mechanisms for delivery of compositions that are highly thinned (i.e., very low viscosity), such a composition would run off of a surface on which it is sprayed, and therefore would not conflict with the subject matter recited in the pending claims. It is important to note that the subject matter of the pending claims of the present application, as amended, is directed to unique compositions that include a solid particulate material, and that have a specified combination of physical properties whereby, upon application of a coating of the composition to a skin treatment area, the coating “does not run off the skin treatment area.” The cited references do not describe any compositions that meet the recited properties of sprayability and run-off resistance, that include solid particulate material and that are delivered using a non-aerosol spray delivery mechanism, as recited in the pending claims. Applicant submits that neither Heilig, nor any other reference of record, teaches or suggests this unique combination of features.

Moreover, Applicant submits that a person of ordinary skill in the art at the time the present application was filed would not have had an expectation that he or she could successfully provide a composition as recited in the pending claims that would be sprayable using a non-aerosol spray delivery mechanism. In particular, no expectation of success can

be derived from mere identification in the prior art of ingredients in a diaper rash treatment composition having significantly different physical properties and delivered using significantly different delivery mechanisms. Rather, there would be no expectation upon consideration of the prior art that any combination of ingredients described therein would have the properties of sprayability and run-off resistance recited in the pending claims. The rheological properties necessary to provide a non-aerosol spray dispensation system capable of atomizing a diaper rash treatment composition including a particulate solid material, while also providing for retention of the composition on the skin treatment area after delivery, are not taught, described or suggested in the cited references, nor are these features exhibited by the compositions described therein.

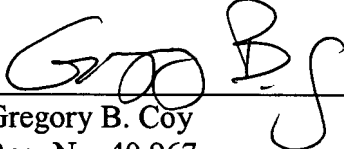
In view of the above, Applicant submits that none of the combinations asserted in the outstanding Action supports a rejection of the claims of the present application under 35 U.S.C. §103. Withdrawal of these rejections is therefore respectfully requested.

**Closing**

In view of the above, Applicant respectfully submits that the rejections stated in the outstanding Action are overcome and that the present application, including claims 39-53, 57, 60, 74-76 and 87-94, is in condition for allowance. Action to that end is respectfully requested. If there are any remaining issues that can be addressed telephonically, the Examiner is invited to contact the undersigned to discuss the same.

Respectfully submitted,

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